

Jerry G. Blaivas, M.D.

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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF WEST VIRGINIA

AT CHARLESTON

-----;

IN RE ETHICON, INC., PELVIC :

REPAIR SYSTEM PRODUCTS : MASTER FILE

LIABILITY LITIGATION : No. 2:12-MD-02327

-----;

:

THIS DOCUMENT RELATES TO : MDL 2327

ALL WAVE 3 CASES :

:

JOSEPH R. GOODWIN

: US DISTRICT JUDGE

- - -

August 29, 2016

- - -

DEPOSITION of JERRY G. BLAIVAS,

M.D., commencing at 12:00 p.m. on the above

date at Urocenter of New York, 445 East 77th

Street, New York, New York, before Marie Foley,

a Registered Merit Reporter, Certified Realtime

Reporter and Notary Public of the State of New

York.

- - -

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A P P E A R A N C E S:

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TRANSCRIPT INDEX

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E X H I B I T S

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NO.	DESCRIPTION	PAGE
Blaivas	Rule 26 Expert Report of	8
Exhibit 1	Jerry G. Blaivas, M.D.	
	dated February 1, 2016	
Blaivas	Notice To Take Deposition	93
Exhibit 2	of Jerry Blaivas, M.D.	
	dated August 25, 2016	
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Exhibit 3	Deposition of Jerry	
	Blaivas, M.D. dated August	
	29, 2016	

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<p style="text-align: right;">Page 5</p> <p>1 DEPOSITION SUPPORT INDEX</p> <p>2</p> <p>3 DIRECTION TO WITNESS NOT TO ANSWER</p> <p>4 Page Line</p> <p>5 - -none- -</p> <p>6</p> <p>7</p> <p>8 REQUEST FOR PRODUCTION OF DOCUMENTS</p> <p>9 Page Line</p> <p>10 - -none- -</p> <p>11</p> <p>12</p> <p>13 STIPULATIONS</p> <p>14 Page Line</p> <p>15 - -none- -</p> <p>16</p> <p>17</p> <p>18 QUESTIONS MARKED</p> <p>19 Page Line</p> <p>20 - -none- -</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 6</p> <p>1 - - -</p> <p>2 1:12 p.m.</p> <p>3 New York, New York</p> <p>4 - - -</p> <p>5 JERRY G. BLAIVAS, M.D., the Witness herein,</p> <p>6 having been first duly sworn by a Notary</p> <p>7 Public in and of the State of New York,</p> <p>8 was examined and testified as follows:</p> <p>9 EXAMINATION BY</p> <p>10 MS. FITZPATRICK:</p> <p>11 Q. Good afternoon, Dr. Blaivas.</p> <p>12 You have never given a</p> <p>13 deposition in the TVT-Exact Wave case, a</p> <p>14 general deposition, correct?</p> <p>15 A. That's correct.</p> <p>16 Q. And has Ethicon previously asked</p> <p>17 you to provide a date for the deposition</p> <p>18 in your TVT-Exact Wave report?</p> <p>19 A. They have.</p> <p>20 Q. Did you offer them the date of</p> <p>21 today, August 29th, at 12:00 for that</p> <p>22 deposition?</p> <p>23 A. I did.</p> <p>24 Q. Did you spend time prior to</p>
<p style="text-align: right;">Page 7</p> <p>1 today preparing for that TVT-Exact</p> <p>2 deposition?</p> <p>3 A. Of course.</p> <p>4 Q. Did you prepare to discuss the</p> <p>5 opinions that you have offered</p> <p>6 specifically in your TVT-Exact report</p> <p>7 today?</p> <p>8 A. I did.</p> <p>9 Q. And do many of the opinions that</p> <p>10 are contained in the TVT-Exact report</p> <p>11 overlap with the opinions that you have</p> <p>12 also given in the TVT Retropubic, TVT-O</p> <p>13 and TVT-S and TVT Abbrevio reports?</p> <p>14 A. They do.</p> <p>15 Q. In addition to that, there are</p> <p>16 some new opinions that you offer that are</p> <p>17 specific to the TVT-Exact as well,</p> <p>18 correct?</p> <p>19 A. Yes.</p> <p>20 Q. At some point this morning, were</p> <p>21 you made aware that Ethicon had</p> <p>22 unilaterally cancelled your deposition in</p> <p>23 this TVT-Exact matter?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 8</p> <p>1 Q. When was that?</p> <p>2 A. Several hours ago.</p> <p>3 Q. We are going ahead because</p> <p>4 Ethicon has waived its right to ask you</p> <p>5 any questions in relation to your report</p> <p>6 in that particular product, but I am here</p> <p>7 representing the plaintiffs and I'm going</p> <p>8 to ask you a series of questions related</p> <p>9 to the opinions in your TVT-Exact report,</p> <p>10 some of which also apply to other products</p> <p>11 as well.</p> <p>12 Do you understand that?</p> <p>13 A. I do.</p> <p>14 Q. Now, you offered a report in the</p> <p>15 TVT-Exact approximately in April of this</p> <p>16 year; is that right?</p> <p>17 A. Yes.</p> <p>18 MS. FITZPATRICK: I'm going to</p> <p>19 go ahead and mark this as Deposition</p> <p>20 Exhibit Number 1.</p> <p>21 (Blaivas Exhibit 1, Rule 26</p> <p>22 Expert Report of Jerry G. Blaivas,</p> <p>23 M.D. dated February 1, 2016, was</p> <p>24 marked for identification, as of this</p>

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<p style="text-align: right;">Page 9</p> <p>1 date.)</p> <p>2 BY MS. FITZPATRICK:</p> <p>3 Q. Doctor, what you have in front</p> <p>4 of you is a report in the TVT-Exact cases,</p> <p>5 correct?</p> <p>6 A. Correct.</p> <p>7 Q. Now, before we get to specifics</p> <p>8 of some of your opinions, I want to</p> <p>9 discuss with you some of your</p> <p>10 qualifications and some of the bases for</p> <p>11 the opinions that you have offered in this</p> <p>12 report.</p> <p>13 You clinically treat women who</p> <p>14 have stress urinary incontinence, correct?</p> <p>15 A. I do.</p> <p>16 Q. Approximately how many women</p> <p>17 have you treated who deal with stress</p> <p>18 urinary incontinence?</p> <p>19 A. Oh, my goodness. Thousands.</p> <p>20 Q. Do you offer surgical</p> <p>21 alternatives to women who present to you</p> <p>22 with stress urinary incontinence?</p> <p>23 A. Of course.</p> <p>24 Q. And what are those surgical</p>	<p style="text-align: right;">Page 10</p> <p>1 alternatives?</p> <p>2 A. Well, I start with simple</p> <p>3 advice. I mean, to start with, all -- I'm</p> <p>4 sorry, with surgical alternatives?</p> <p>5 Q. Surgical alternatives, yes.</p> <p>6 A. Okay. Surgical alternatives, I</p> <p>7 prefer the autologous sling when the</p> <p>8 patient is ready for invasive surgery, but</p> <p>9 I offer everybody periurethral injections</p> <p>10 to the extent that it's appropriate.</p> <p>11 Q. Okay. And, in addition to your</p> <p>12 treatment of women who have stress urinary</p> <p>13 incontinence, do you also treat women who</p> <p>14 present to you with complications</p> <p>15 following an implantation of polypropylene</p> <p>16 midurethral slings?</p> <p>17 A. I do.</p> <p>18 Q. Can you tell me over the course</p> <p>19 of your practice approximately how many</p> <p>20 women you have treated for complications</p> <p>21 arising after the implantation of</p> <p>22 polypropylene slings?</p> <p>23 A. Well, I've participated in the</p> <p>24 care of many hundreds and I've operated on</p>
<p style="text-align: right;">Page 11</p> <p>1 probably about a hundred.</p> <p>2 Q. For those women who present to</p> <p>3 you with complications or symptoms</p> <p>4 following the implantation of a</p> <p>5 polypropylene sling, do you go through a</p> <p>6 differential diagnosis with them to</p> <p>7 determine whether the polypropylene</p> <p>8 midurethral sling is a cause of their</p> <p>9 symptoms or not?</p> <p>10 A. Of course.</p> <p>11 Q. And in all of the women who have</p> <p>12 presented to you with complications</p> <p>13 following the implantation of the</p> <p>14 polypropylene midurethral sling, you</p> <p>15 haven't always concluded that the</p> <p>16 polypropylene midurethral sling is a cause</p> <p>17 of those complications, correct?</p> <p>18 A. Yes.</p> <p>19 Q. Can you tell me what you do to</p> <p>20 distinguish between complications that are</p> <p>21 associated with polypropylene midurethral</p> <p>22 sling versus complications or symptoms</p> <p>23 that arise just in time following the</p> <p>24 implantation?</p>	<p style="text-align: right;">Page 12</p> <p>1 A. Are you talking about people who</p> <p>2 only have had slings? Because some</p> <p>3 patients have slings and prolapse repairs.</p> <p>4 Q. Either one. I just want you to</p> <p>5 describe your methodology that you go</p> <p>6 through to determine whether the</p> <p>7 complications are associated with the</p> <p>8 polypropylene mesh or not.</p> <p>9 A. I don't -- I'm not sure I think</p> <p>10 of it exactly that way. I define what the</p> <p>11 complication is and then what the cause</p> <p>12 could be. So, just in order of things</p> <p>13 that can happen, if a patient has</p> <p>14 difficulty voiding, it could be the sling</p> <p>15 or it could be what we call an acquired</p> <p>16 voiding dysfunction, and I make that</p> <p>17 distinction based on examination of the</p> <p>18 patient, the urinary flow rate, and</p> <p>19 examination for obstruction.</p> <p>20 Q. Let me ask you for an</p> <p>21 obstruction case, you don't just</p> <p>22 necessarily assume that a woman who's had</p> <p>23 polypropylene midurethral sling who then</p> <p>24 has an obstruction that the polypropylene</p>

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<p style="text-align: right;">Page 13</p> <p>1 sling is the cause or the only cause of 2 that obstruction, correct? 3 A. Correct. I mean, we go through 4 a process to make sure that the 5 obstruction is a mechanical obstruction, 6 and if it's a mechanical obstruction, it 7 could be overwhelmingly likely from the 8 sling, but it also could be a urethral 9 diverticulum. It could also be a Grade 3 10 or 4 prolapse, but sometimes it's just 11 what we call an acquired voiding 12 dysfunction where they get into sort of a 13 bad habit and sometimes it can be a very 14 weak bladder, a weak detrusor contraction. 15 Q. Is it fair to say, Doctor, in 16 your clinical practice, you employ 17 differential diagnosis and look at each 18 woman individually to determine whether 19 the mesh is or is not a cause of her 20 symptoms in each individual case? 21 A. Of course. 22 Q. And is it fair to say in your 23 clinical practice you see some women who 24 have complications and you determine they</p>	<p style="text-align: right;">Page 14</p> <p>1 are not caused by the polypropylene 2 midurethral sling? 3 A. Yes. 4 Q. And it's fair to say that in 5 your clinical practice, there are times 6 that you diagnose women's complications as 7 being related to the polypropylene 8 midurethral sling that they have? 9 A. Yes. 10 Q. When a woman presents to you 11 with a complication that you then 12 determine after examination is caused by a 13 midurethral sling, what treatment options 14 do you offer to that woman? 15 A. Well, it depends what the 16 complication is. Generally, and these are 17 very -- you know, it depends what the 18 complication is. If it's clearly an 19 obstruction from the sling, and when there 20 is an obstruction that's what it usually 21 is, then my recommendation is that we 22 remove the entire suburethral portion of 23 the sling. 24 If the complication is a</p>
<p style="text-align: right;">Page 15</p> <p>1 fistula, then we remove all of the sling, 2 all of the sub -- all of the sling that's 3 in the vicinity of the urethra -- excuse 4 me, of the fistula and then repair the 5 fistula. 6 If it's pain, then it depends 7 where the pain is, and again I don't have 8 to go into the particulars, but sometimes 9 we just remove that portion that appears 10 to be related or causing the pain, but 11 sometimes we remove the entire mesh 'cause 12 I think the entire mesh is causing the 13 pain. 14 If it's overactive bladder 15 symptoms, we -- if it's due to urethral 16 obstruction, we remove the suburethral 17 portion. If we're not -- if it seems like 18 it's in the wall of the bladder but -- or 19 through the wall of the bladder, then we 20 remove all of the sling on that side and 21 sometimes the entire sling. 22 Q. Is it fair to say based on what 23 you've just told me that the treatment 24 options that you offer are tailored to a</p>	<p style="text-align: right;">Page 16</p> <p>1 woman's specific problems? 2 A. Of course. 3 Q. And would you say that you try 4 to treat the problems as conservatively as 5 possible, with the least amount of surgery 6 necessary to correct those problems? 7 A. No, I would say I try to be 8 appropriate. I mean, sometimes it's 9 appropriate to be conservative. Sometimes 10 it's appropriate to be radical, but I 11 discuss it with the patient. 12 Q. Okay. Now, in addition to your 13 clinical work and your clinical 14 experience, you also have done academic 15 work and published articles concerning 16 mesh and mesh complications, correct? 17 A. I have. 18 Q. And most recently you published 19 an article entitled "Safety Considerations 20 for Synthetic Sling Surgery" that was 21 published in the Nature Reviews of Urology 22 in 2015, correct? 23 A. Yes. 24 Q. And you were a co-author on that</p>

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<p style="text-align: right;">Page 17</p> <p>1 with eight other individuals, correct?</p> <p>2 A. Yes.</p> <p>3 Q. Can you tell me, first of all,</p> <p>4 how this article came to be?</p> <p>5 A. Well, Nature Reviews in Urology</p> <p>6 is a highly respected peer review journal,</p> <p>7 and they, for their reviews they actually</p> <p>8 solicit authors. I don't believe you can</p> <p>9 just submit. I'm not sure of that.</p> <p>10 But they asked me to do a review</p> <p>11 article, and they told me right up front</p> <p>12 that just because I agreed to do it, it</p> <p>13 did not mean that it would be automatically</p> <p>14 accepted.</p> <p>15 Q. Now, can you tell us what a</p> <p>16 review article is?</p> <p>17 A. A review article is, there are</p> <p>18 lots of different types, but basically</p> <p>19 it's a compilation of many and sometimes</p> <p>20 all of the articles in the peer review</p> <p>21 literature about a certain topic. And</p> <p>22 then, so the first thing that you do is</p> <p>23 you -- is you do a literature search and</p> <p>24 you identify the articles and then you use</p>	<p style="text-align: right;">Page 18</p> <p>1 search criteria to eliminate certain</p> <p>2 articles and then you analyze them based</p> <p>3 on whatever methodology you choose.</p> <p>4 Q. So, let me discuss, you were</p> <p>5 approached by Nature and asked to conduct</p> <p>6 a review on the literature available</p> <p>7 concerning synthetic sling surgery,</p> <p>8 correct?</p> <p>9 A. Yes.</p> <p>10 Q. And, I see that we mentioned you</p> <p>11 have a number of other authors here.</p> <p>12 Are those authors that you asked</p> <p>13 to help you with this, or are those</p> <p>14 authors that Nature assigned to this</p> <p>15 project?</p> <p>16 A. No, I got to select my team.</p> <p>17 Q. Can you tell me how you went</p> <p>18 about selecting the team?</p> <p>19 A. Sure. Well, okay, so, two of</p> <p>20 the co-authors, Robert Bendavid and</p> <p>21 Vladimir Latovlev, L-A-T-O-V-L-E-V, are</p> <p>22 recognized authorities in the field, and I</p> <p>23 asked them if they would be willing to</p> <p>24 help me with this.</p>
<p style="text-align: right;">Page 19</p> <p>1 One of them, Roger Purohit,</p> <p>2 P-U-R-O-H-I-T, is my partner, so we</p> <p>3 operate together and he has a considerable</p> <p>4 amount of clinical experience. And then</p> <p>5 Matt Benden and Gabriel Mekel, M-E-K-E-L,</p> <p>6 and Michael Stern and Mubashir Billah,</p> <p>7 B-I-L-L-A-H, and I'll have to spell the</p> <p>8 other ones, K-O-L-A is the first name and</p> <p>9 it's O-L-U-G-B-A-D-E, were all students</p> <p>10 that -- well, actually, Dr. Mekel was</p> <p>11 doing a fellowship with me and the others</p> <p>12 are either medical students, or are all</p> <p>13 medical students.</p> <p>14 Q. Okay. When did Nature approach</p> <p>15 you about authoring a review on synthetic</p> <p>16 sling surgery?</p> <p>17 A. It was some time after May of, I</p> <p>18 guess, 20 -- I don't know if it was 2013</p> <p>19 or -- probably -- or 2014. I can't</p> <p>20 remember.</p> <p>21 Q. Okay.</p> <p>22 A. But it was after the American</p> <p>23 Urologic Association national meeting.</p> <p>24 Q. Did anyone from Nature tell you</p>	<p style="text-align: right;">Page 20</p> <p>1 why they selected you or asked you to</p> <p>2 write this article over others?</p> <p>3 A. Well, yes, they had heard --</p> <p>4 one, they heard about me, they knew of me</p> <p>5 and they asked around and they asked who</p> <p>6 would be a good person to do it, and I</p> <p>7 believe someone had seen me participate in</p> <p>8 a debate at the annual meeting of the</p> <p>9 American Urologic Association.</p> <p>10 Q. Was there any kind of</p> <p>11 preconceived outcome that anyone had</p> <p>12 discussed with you of what they expected</p> <p>13 your research to show or not show?</p> <p>14 A. No.</p> <p>15 Q. Now, this article that you did,</p> <p>16 a review article, does not contain all of</p> <p>17 the articles available in the medical</p> <p>18 literature that reference or concern</p> <p>19 midurethral slings, correct?</p> <p>20 A. Correct.</p> <p>21 Q. How did you and your co-authors</p> <p>22 determine and choose the articles that you</p> <p>23 relied on for this particular piece?</p> <p>24 A. Well, two ways. One, and I'm</p>

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<p style="text-align: right;">Page 21</p> <p>1 sorry, I don't have all the details in my 2 memory, but there was an article 3 published -- there was another review 4 article that I thought was timely that did 5 a review up to a certain date and then 6 we -- I just decided to do it from about 7 that time to the what was then current, 8 which was 2014. And I can tell you in a 9 minute what the dates were. 10 Q. Sure. 11 (Pause.) 12 A. So, it was from 2007 to 2014. 13 Excuse me, that was for the 14 clinical review, okay. Dr. Latovlev 15 independently reviewed the pathology which 16 went back many years before that. 17 Q. One of the things that I want to 18 talk to you about today is the conclusions 19 that you reached concerning the 20 complications and the complication rates 21 associated with midurethral slings. 22 Would that be included in the 23 clinical review that you just mentioned? 24 A. Yes.</p>	<p style="text-align: right;">Page 22</p> <p>1 Q. So, you and your co-authors 2 chose articles written from 2007 to 2014, 3 and I think what you mentioned to me 4 before was that there's certain search 5 criteria that you use when conducting your 6 literature search to determine what 7 articles would be included in a review 8 article; is that right? 9 A. Yes. 10 Q. And can you tell me what the 11 search criteria that you and your 12 co-authors were? 13 A. It's a long list. Shall I read 14 it to you? 15 Q. Sure. 16 A. Okay. So, the search combined 17 the terms, and some of these are just 18 spelling things. So, there was 19 midurethral slings where "mid" and 20 "urethral" are two words; midurethral 21 slings where "midurethral" is one word; 22 suburethral sling, urethral sling, 23 midurethral slings with a plural, both 24 words again with a plural. All of the</p>
<p style="text-align: right;">Page 23</p> <p>1 words that I just said also in plural. 2 Follow-up study, other than all of those 3 terms and follow-up study. 4 Also, we used free text searches 5 including the terms urinary 6 incontinence -- excuse me, TVT, tension 7 free vaginal tape, tension free vaginal 8 sling, transobturator tape, transobturator 9 sling, TVT-Obturator, TVT-O, TVT Secure, 10 Minarc, that's M-I-N-A-R-C, Abbrevio, 11 A-B-B-R-E-V-I-O, TOT, suprapubic arc 12 sling, Sparc, S-P-A-R-C, sling, 13 intravaginal slingplasty, IVS sling, RAZ, 14 R-A-Z, sling, Uratape, that's 15 U-R-A-T-A-P-E, ObTape, O-B-T-A-P-E, 16 prepubic sling, prepubic TVT, prepubic 17 tape, Pelvilace, P-E-L-V-I-L-A-C-E, 18 ureter, Aris, A-R-I-S, In-Fast, 19 I-N-F-A-S-T, Monarc I-STOP, urethral 20 reconstruction, urethral vaginal fistula, 21 other spelling of ObTape, Gore-Tex sling, 22 silastic sling, Mersilene sling, Marlex 23 sling, vesicovaginal fistula, Bioarc. And 24 then -- yeah, so that was the search that</p>	<p style="text-align: right;">Page 24</p> <p>1 we did on the clinical end. 2 Q. Okay. And that sounds like 3 quite a number of search terms; is that 4 right? 5 A. Yes. 6 Q. Why did you have so many search 7 terms? 8 A. 'Cause we didn't want to miss 9 any articles, and what we did is we would 10 look up -- we started with less search 11 terms and as we read articles, we would 12 see synonyms or new words and then we 13 would add that to the search term. 14 Q. Did you limit the types of 15 articles you were looking at? For 16 example, did you only look at randomized 17 control trials or only look at 18 meta-analyses or only look at case 19 studies? 20 A. No, we did not limit it. 21 Q. Is it fair to say that you were 22 trying to get as big a cross-section or as 23 big a representation of all of the 24 articles out there and kind of gather them</p>

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<p style="text-align: right;">Page 25</p> <p>1 up before you got started with this 2 process? 3 A. Yes. I just remembered there 4 was actually, there was one exclusion 5 criteria that we used. If an article by 6 the same authors seemed to include the 7 same patients in a different study, we 8 would have used the most -- either the 9 most recent one or the most appropriate 10 one. We tried not to count the same 11 patients twice. 12 Q. Okay. 13 A. So if one author had a 14 patient -- had a study that showed the 15 patients at one year, five years, 10 16 years, 15 years and 20 years, and they had 17 complications, we wouldn't count the 18 complications five times. We'd only count 19 the complications once. 20 Q. Okay. Is it fair to say that 21 you were attempting to count each patient 22 one time and not duplicate those patients 23 or those complications in your analysis at 24 all?</p>	<p style="text-align: right;">Page 26</p> <p>1 A. Exactly. 2 Q. And the method that you used to 3 do that by only using one article from a 4 series, is that a standard acceptable way 5 of achieving that goal when doing medical 6 or scientific research? 7 A. You know, I don't know. 8 Q. Tell me why you thought that it 9 was an appropriate way to achieve that 10 result. 11 A. Because I wanted to be sure on 12 the one hand that we captured every 13 complication, but on the other hand we 14 didn't count anybody twice 'cause we were 15 looking to get as precise a number for 16 both -- for complications as we could. We 17 didn't want to overestimate; we didn't 18 want to underestimate. 19 Q. Okay. And that's for the 20 clinical portion, and clinically you 21 looked at both the safety of the product, 22 correct, the complications? 23 A. Yes. 24 Q. And you also looked at the</p>
<p style="text-align: right;">Page 27</p> <p>1 efficacy of the product, correct? 2 A. Yes. 3 Q. Was there different criteria 4 that you looked at for articles relating 5 to efficacy? 6 A. Yes. For articles for efficacy 7 we only included those articles that 8 measured efficacy, that had appropriate 9 follow-up, and we did have criteria for 10 that. 11 Q. Is that different from -- it 12 sounds like you had more exclusion 13 criteria for the efficacy articles than 14 you did the complication/safety articles; 15 is that right? 16 A. Yes. 17 Q. Is there anything else that you 18 excluded beyond, from your literature 19 search, beyond the subsequent articles or 20 the multi-reported cases? 21 A. Yes. The only other exclusion 22 was non-human subjects. 23 Q. Did you in any way cherry pick 24 or look only for reports or articles that</p>	<p style="text-align: right;">Page 28</p> <p>1 dealt with high rates of complications? 2 A. No. 3 Q. Did you only look for articles 4 that reported low rates of complications? 5 A. No. We intend -- to the best of 6 our ability, we picked every article in 7 the literature in that time period. 8 Q. And that are articles that 9 reflected some lower rates of 10 complications, correct? 11 A. Of course. 12 Q. And articles that reflected 13 higher rates of complication, correct? 14 A. Yes. 15 Q. And fair to say it included case 16 studies? 17 A. Yes, it did. 18 Q. It included randomized control 19 trials? 20 A. Yes. 21 Q. It included meta-analyses? 22 A. Yes. 23 Q. Is there anything at all that 24 you or your co-authors did to limit or</p>

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<p style="text-align: right;">Page 29</p> <p>1 exclude certain articles or certain 2 findings in articles that would otherwise 3 have been encompassed in your search 4 terms? 5 A. Only for the efficacy studies. 6 Q. Okay. Now -- 7 A. And that -- but those were a 8 search term, so we -- so I guess the 9 answer is no, we did not. Okay. 10 Q. Now, could somebody look at what 11 you've reported in Table 1 relating to the 12 efficacy issues and extrapolate in any way 13 what you did there and apply it to the 14 complication tables that you reflected in 15 Table 2, 3, 4 and 5? 16 A. No, you couldn't because they 17 didn't apply -- none of these -- well, 18 most of these studies did not have any 19 scientifically valid prospective way of 20 looking at complications. This was just 21 for efficacy. 22 Q. Is there any way that someone 23 could -- 24 MS. FITZPATRICK: Let me ask it</p>	<p style="text-align: right;">Page 30</p> <p>1 a different way. 2 Q. Is it correct that there are 3 articles that you considered for your 4 safety considerations or complication 5 rates that are not reflected in the table 6 concerning efficacy? 7 A. Probably not because we would 8 always -- no, because we would -- we 9 would -- if there was even one 10 complication, we would -- we would have 11 included it. 12 Q. But just because you had it, and 13 I think what you're telling me is all of 14 your efficacy articles were included in 15 your complication analysis, and I'm 16 actually asking the opposite. 17 Were all of the articles that 18 you considered for the complication part 19 all used also to look at efficacy? 20 A. No. 21 Q. So you can't say that simply 22 because something isn't on the Table 1 23 that you didn't rely on it, use it, 24 conclude anything about it or consider it</p>
<p style="text-align: right;">Page 31</p> <p>1 as part of your safety considerations and 2 complication considerations; is that 3 right? 4 A. To the contrary; we would have 5 used it. 6 Q. Okay. Now, this article went 7 through the peer review process, correct? 8 A. Very much so. 9 Q. Can you tell me what you mean by 10 that? 11 A. Well, the peer review process 12 itself is designed to insure that the 13 highest standards of scientific 14 methodology were used in the paper and 15 very specifically that the results and the 16 conclusions follow from the methodology; 17 i.e. that the conclusions follow from the 18 methods. 19 Q. Is there anything that was 20 different about the Nature peer -- 21 MS. FITZPATRICK: Strike that. 22 Q. You've worked as a peer reviewer 23 before, correct, for other journals? 24 A. Yes.</p>	<p style="text-align: right;">Page 32</p> <p>1 Q. And you've also been editor of a 2 journal that is a peer review journal, 3 correct? 4 A. Yes. 5 Q. Can you tell me generally in the 6 medical and scientific community how 7 individuals get selected as peer 8 reviewers? 9 A. Sure. They get selected by a 10 process of usually by a committee of 11 experts that picks other experts that they 12 think contribute to the peer review 13 process. So they have to show -- they 14 have to be held in high regard as experts 15 that can give a fair and unbiased 16 appraisal of submissions. 17 Q. Do you know of any peer review 18 publication that has considered the 19 opinions of attorneys from medical device 20 manufacturers as part of peer review 21 process? 22 A. No, I do not. 23 Q. Why aren't attorneys for medical 24 device manufacturers qualified to serve as</p>

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<p style="text-align: right;">Page 33</p> <p>1 peer reviewers for a medical journal?</p> <p>2 A. Well, the most obvious reason is</p> <p>3 that their opinions were likely to be</p> <p>4 biased or that they have a major conflict</p> <p>5 of interest and they don't fulfill our</p> <p>6 criteria for being an expert. They're</p> <p>7 lawyers; they're not experts in</p> <p>8 scientific research.</p> <p>9 Q. Is it fair to say that the peer</p> <p>10 review process is designed to have</p> <p>11 neutral, objective, experienced</p> <p>12 individuals assessing the methodology and</p> <p>13 the conclusions that are reached in</p> <p>14 medical and scientific journals?</p> <p>15 A. Of course.</p> <p>16 Q. That process is designed to</p> <p>17 insure that the methodology that is used</p> <p>18 is something that is recognized and</p> <p>19 acceptable in the medical and scientific</p> <p>20 community, correct?</p> <p>21 A. Yes.</p> <p>22 Q. In your experience as both a</p> <p>23 peer reviewer and as an editor of a peer</p> <p>24 review journal, what happens in the</p>	<p style="text-align: right;">Page 34</p> <p>1 process if an article is presented that</p> <p>2 does not use established accepted</p> <p>3 methodology in the scientific and medical</p> <p>4 community?</p> <p>5 A. Well, as a general rule, it's</p> <p>6 rejected. On rare occasions, someone</p> <p>7 comes up with such a novel approach that</p> <p>8 even though that it wasn't known before,</p> <p>9 it might become -- it might be acceptable.</p> <p>10 Q. Do you believe that the peer</p> <p>11 review -- let me ask you this.</p> <p>12 Tell me about the peer review</p> <p>13 process that you went through for your</p> <p>14 Nature article.</p> <p>15 A. This was the most rigorous peer</p> <p>16 review that I've ever been part of. I</p> <p>17 mean, we -- this article took more time</p> <p>18 and more effort than any article I've ever</p> <p>19 written, and I, you know, I've done</p> <p>20 hundreds and hundreds. So it was a very</p> <p>21 labor intense project. We read all of the</p> <p>22 articles, and then when we wrote the</p> <p>23 articles, we submitted it and they had a</p> <p>24 number of questions, concerns, suggested</p>
<p style="text-align: right;">Page 35</p> <p>1 revisions and it went back and forth a</p> <p>2 number of times to be sure that we -- that</p> <p>3 our -- to be sure, quite honestly, that</p> <p>4 our, as I mentioned a few minutes ago is</p> <p>5 that our results and conclusions were</p> <p>6 clearly supported by the methodology and</p> <p>7 that they were scientifically sound.</p> <p>8 Q. Do you believe, Doctor, that the</p> <p>9 fact that your article in Nature Review</p> <p>10 survived the peer review process</p> <p>11 establishes that the methodology that you</p> <p>12 and your co-authors used in that, in</p> <p>13 drafting that article, was scientifically</p> <p>14 reliable?</p> <p>15 A. I do.</p> <p>16 Q. Would it be widely considered in</p> <p>17 your medical community that an article</p> <p>18 such as yours that has gone through such a</p> <p>19 rigorous peer review process has</p> <p>20 demonstrated appropriate medical and</p> <p>21 scientific methodology?</p> <p>22 A. Yes.</p> <p>23 Q. Has anybody in the medical</p> <p>24 community or at Nature questioned your</p>	<p style="text-align: right;">Page 36</p> <p>1 methodology in connection with that</p> <p>2 article at any time prior to its</p> <p>3 publication?</p> <p>4 A. Well, they asked questions about</p> <p>5 it in the review process, but I don't --</p> <p>6 but afterwards, no, I don't -- I'm not</p> <p>7 aware of anybody questioning it.</p> <p>8 Q. And are you comfortable that the</p> <p>9 Nature Review Urology looked closely at</p> <p>10 the methodology that you and your</p> <p>11 co-authors used to reach the conclusions</p> <p>12 that you did in that review paper?</p> <p>13 A. I'm quite confident of that.</p> <p>14 Q. We're going to talk in a little</p> <p>15 bit specific about some of the conclusions</p> <p>16 in that article and I'm going to ask you</p> <p>17 more specifically how you reached the</p> <p>18 conclusions that you did.</p> <p>19 But, in addition to the</p> <p>20 conclusions that you reached in that</p> <p>21 article, you also rely on your clinical</p> <p>22 experience for an independent basis of</p> <p>23 your TVT-Exact report, correct?</p> <p>24 A. Yes.</p>

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<p style="text-align: right;">Page 37</p> <p>1 Q. And including those portions 2 that overlap with the other polypropylene 3 midurethral sling products that you've 4 offered reports on, correct? 5 A. Yes. 6 Q. In addition to your Nature 7 article, in addition to your clinical 8 experience, did you also rely on 9 peer-reviewed literature which was 10 identified both in the footnotes of your 11 report and then in the reliance list that 12 you provided with that report? 13 A. I did. 14 Q. In selecting that peer-reviewed 15 literature for inclusion in your report or 16 your reliance list, were there any 17 articles that you just dismissed out of 18 hand and refused to consider when reaching 19 the opinions that you have in this case? 20 A. I don't dismiss them out of 21 hand. I mean, there's some that I don't 22 agree with the methodology. 23 I mean, are you asking in 24 general?</p>	<p style="text-align: right;">Page 38</p> <p>1 Q. Would you ever look at an 2 article and say well, there's only a .1 3 complication rate, so I'm not even going 4 to look or consider that article? 5 A. No, I don't do that. 6 Q. Tell me what you do when you 7 look at articles to determine that you 8 think, or what weight you should be giving 9 to those particular articles. 10 A. Generally, first thing I do is 11 look at the results of the -- basically I 12 basically look at the conclusions first 13 and then I look at the methodology and 14 say -- confirm that the conclusions could 15 be justified by the methodology. If the 16 methodology is such that it can't even 17 answer the questions that the conclusions 18 concluded, I would still look at the 19 paper, but I would -- I would tend to not 20 read that in great depth. And then if the 21 two go hand in hand, then I look at the 22 results and make sure that the results 23 follow from the methods as well. 24 Q. In your both clinical and</p>
<p style="text-align: right;">Page 39</p> <p>1 academic practice, do you regularly and 2 routinely read articles that appear in the 3 medical and scientific literature about 4 polypropylene slings? 5 A. I do. 6 Q. Are those also brought to your 7 attention by colleagues of yours? 8 A. Yes. 9 Q. Do you consider all of those 10 articles as part of -- 11 MS. FITZPATRICK: Excuse me. 12 Q. Do you consider all of those 13 articles prior to reaching the conclusions 14 that you've set forth in your expert 15 report? 16 A. I consider them, yes. 17 Q. Okay. Now, I want to ask you a 18 couple of questions, specifically about 19 what's in your report. 20 In paragraph 17 of your report 21 that you have in front of you, you note 22 that it is common for trocars to puncture 23 the bladder or urethra during trocar 24 passage.</p>	<p style="text-align: right;">Page 40</p> <p>1 A. Yes. 2 Q. Do you see that? 3 A. I do. 4 Q. Looking at your Nature article, 5 you also looked at incidents of bladder 6 and transvaginal trocar perforation, some 7 of the complications that were reported in 8 the medical literature, correct? 9 A. I do. 10 Q. Let's start with do you rely on 11 any of your clinical experience for your 12 opinion that it is common for trocars to 13 puncture the bladder or urethra during 14 trocar passage? 15 A. I do. 16 Q. And how does your clinical 17 experience specifically support your 18 opinion that it is common for trocars to 19 puncture the bladder or urethra during 20 trocar passage? 21 A. Well, from my clinical 22 experience, when I -- first of all, I talk 23 to a lot of my peers and colleagues about 24 it and I simply ask them in the hospital.</p>

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<p style="text-align: right;">Page 41</p> <p>1 I -- in over two thousand cases that I've 2 done without mesh, there's only been one 3 time that I perforated the -- the bladder, 4 and when that happened, I was personally 5 really taken aback and I kind of made a 6 big deal about it. And the resident said, 7 "What are you doing? Why are you so 8 upset?" I said, "Geez, well, we just 9 perforated the bladder." And the resident 10 said, "Well, yeah, happens all the time 11 with -- it happens all the time with the 12 midurethral slings." That's one -- that's 13 one point of information. 14 Second is, as I mentioned, I 15 talk to my colleagues and my peers a lot 16 about this stuff and they, virtually all 17 of them, almost all of them say that it 18 does happen periodically that they 19 perforate the bladder. 20 Q. But -- 21 A. And then -- 22 Q. Sorry. Go ahead. 23 A. And then finally, I've seen 24 hundreds of patients that have had</p>	<p style="text-align: right;">Page 42</p> <p>1 complications from slings, and when I 2 review those operative notes, they not 3 infrequently say that they perforated the 4 bladder. 5 Q. Okay. 6 A. And then took it out and passed 7 it again. 8 Q. But you don't rely just on the 9 anecdotal stories from colleagues or 10 looking at your report to reach your 11 opinion that it's common for trocars to 12 puncture the bladder or urethra during 13 passage, correct? 14 A. Of course not. 15 Q. What else do you rely on for 16 that opinion? 17 A. On the published literature. 18 Q. Can you identify any 19 peer-reviewed published literature that 20 you have seen that you rely on to support 21 your opinions that it's common for these 22 punctures to happen? 23 A. Sure. There's an article by 24 Albo, I think it was -- I think it was</p>
<p style="text-align: right;">Page 43</p> <p>1 2012, that was reported in the Journal of 2 Urology that found an incidence of, I 3 forget the exact number, either five or 4 six percent were perforated. And in the 5 AUA guidelines, Roger Dmochowski published 6 that in, he was the lead author, in 20 -- 7 actually, I don't remember the year, but 8 that also had a similar incidence of about 9 five or six percent. 10 Q. Are those the only articles that 11 you rely on? 12 A. No, there's many other ones. 13 Q. And are many of those articles 14 also cited in your reliance list -- 15 A. Yes. 16 Q. -- that you provided in this 17 case? 18 A. Yes. 19 Q. Do you believe that there's 20 sufficient peer-reviewed published 21 literature to support the opinion that 22 it's common for trocars to puncture the 23 bladder or urethra during trocar passage? 24 A. Well, common is in the eyes of</p>	<p style="text-align: right;">Page 44</p> <p>1 the beholder, but I think there's ample 2 literature to show that it happens on the 3 order of magnitude of five percent. In 4 series it's as high as 20 or 30 percent. 5 Q. And is that something that you 6 also looked at in connection with your 7 Nature Review article? 8 A. Yes. 9 Q. Can you tell me what you did in 10 your Nature Review article to look at this 11 incidence of trocar puncture of the 12 bladder or urethra? 13 A. Well, that we just compiled all 14 the articles in the literature because 15 there wouldn't be a case report -- all of 16 the -- all of the articles that were 17 reviewed and we just averaged the -- we 18 gave a range and an average and a mean of 19 how often it was perforated. 20 Q. Okay. So, let me stop you there 21 because I want to talk a little bit more 22 about the methodology that you used not 23 just for calculating trocars, but for 24 calculating all of the rates of</p>

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<p style="text-align: right;">Page 45</p> <p>1 complications.</p> <p>2 Was bladder or urethra puncture</p> <p>3 during trocar passage one of the</p> <p>4 complications that you looked at and</p> <p>5 considered in your Nature Review article?</p> <p>6 A. It was.</p> <p>7 Q. What I'd like you to do is to</p> <p>8 walk me through you and your co-authors</p> <p>9 compile all of the literature that you can</p> <p>10 find from an extensive literature search</p> <p>11 that report any complications or any</p> <p>12 incident of complications from either an</p> <p>13 individual patient or a patient cohort; is</p> <p>14 that correct?</p> <p>15 A. Yes.</p> <p>16 Q. And you looked for everything</p> <p>17 you could find; is that right?</p> <p>18 A. Yes.</p> <p>19 Q. And you didn't exclude any</p> <p>20 articles unless it was a multiple</p> <p>21 reporting of the same cohort?</p> <p>22 A. Or non-humans.</p> <p>23 Q. Or non-humans, okay.</p> <p>24 And your reason for excluding</p>	<p style="text-align: right;">Page 46</p> <p>1 multiple reports of the same cohort is you</p> <p>2 didn't want to double count injuries, so</p> <p>3 therefore potentially inflating the rates</p> <p>4 of complications that you were looking at;</p> <p>5 is that right?</p> <p>6 A. Yes.</p> <p>7 Q. You were attempting to keep it</p> <p>8 one patient counted for one time</p> <p>9 throughout this analysis that you did,</p> <p>10 correct?</p> <p>11 A. Yes.</p> <p>12 Q. So you and your colleagues have</p> <p>13 this massive medical literature in front</p> <p>14 of you.</p> <p>15 What did you do with that</p> <p>16 information to reach the conclusions that</p> <p>17 you reached in your article concerning the</p> <p>18 existence of certain complications and</p> <p>19 then the incidence of those complications?</p> <p>20 A. Well, for the incidence we</p> <p>21 counted every single complication. So, to</p> <p>22 make it simple, if there were only two</p> <p>23 articles, one had a hundred patients and</p> <p>24 no, in this instance, perforations and one</p>
<p style="text-align: right;">Page 47</p> <p>1 was a case report of one complication with</p> <p>2 no denominator because it's just a case</p> <p>3 report, we would use the one as the</p> <p>4 numerator and the denominator would be the</p> <p>5 101.</p> <p>6 Q. Okay.</p> <p>7 A. But of course this was done in</p> <p>8 hundreds of papers, so it was much more</p> <p>9 complicated than that.</p> <p>10 Q. So let me, as a non-scientist</p> <p>11 and non-medical person, let me see if I'm</p> <p>12 right in my understanding.</p> <p>13 You took and counted every</p> <p>14 patient who was included in all of those</p> <p>15 articles and you counted them all up and</p> <p>16 that became your denominator, the total</p> <p>17 number of people who have been studied,</p> <p>18 reported, considered in some way in the</p> <p>19 medical literature as potentially, or as a</p> <p>20 subject in a study about mesh</p> <p>21 complications; is that right?</p> <p>22 A. Yes.</p> <p>23 Q. And then you took that entire</p> <p>24 denominator and then what you did is you</p>	<p style="text-align: right;">Page 48</p> <p>1 went through and you added up each, for</p> <p>2 example in this case, each incident of</p> <p>3 bladder or urethral trocar perforation</p> <p>4 that you could find anywhere in that</p> <p>5 medical literature; is that right?</p> <p>6 A. Yes.</p> <p>7 Q. What did you do with those two</p> <p>8 numbers to reach the percentages in the</p> <p>9 conclusions that you reached?</p> <p>10 A. Well, we just added them up. So</p> <p>11 the numerator is the number and the -- the</p> <p>12 numerator divided by the denominator is</p> <p>13 the percent.</p> <p>14 Q. And that's the methodology that</p> <p>15 was reviewed by the neutral peer reviewers</p> <p>16 for Nature Journal of Urology, correct?</p> <p>17 A. Yes. I mean, we also did -- we</p> <p>18 did it another -- the other way we did it</p> <p>19 is we looked at the range and the averages</p> <p>20 for each -- for when there's a -- when</p> <p>21 there were a series.</p> <p>22 So, if there were two series and</p> <p>23 one had, you know, a hundred patients with</p> <p>24 zero perforations, another one had a</p>

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<p style="text-align: right;">Page 49</p> <p>1 hundred patients with 20 percent, you 2 know, we would say that the range in the 3 different series was zero to 20 percent 4 and the mean of the series was whatever 5 the numbers comes to. 6 Q. So you have two different ways 7 that you've gone about this analysis and 8 the two different methodologies. 9 The first is the adding up all 10 of the individual women who are identified 11 and doing the numerator and the 12 denominator, and you did that specifically 13 for each complication individually, 14 correct? 15 A. Yes. 16 Q. So you'd calculate the number of 17 women who had a bladder perforation 18 separately from the number of women who 19 had a urethral erosion, separate from the 20 number of women who had a pain 21 complication; is that right? 22 A. Yeah, we'd count each of them 23 separately, yeah. 24 Q. And you also broke that down</p>	<p style="text-align: right;">Page 50</p> <p>1 between transobturator slings and 2 retropubic slings, correct? 3 A. Yes. 4 Q. So, in addition to doing that 5 and reflecting those calculations and that 6 methodology, what you also did is you 7 reported on the ranges that you saw from 8 the various articles? 9 A. For the series. 10 Q. Just for the series, not for the 11 case reports, but for the series that -- 12 let me ask you this. 13 Did you look at articles that 14 reflected rates of complications for each 15 of these identified symptoms across a 16 series of patients? 17 A. I'm sorry, I lost my train of 18 thought. Say that again. 19 Q. Sure. 20 Did you also look at the rates 21 of complications that were quantified by 22 other authors in series that they had 23 published in peer-reviewed medical 24 journal?</p>
<p style="text-align: right;">Page 51</p> <p>1 A. We did. 2 I need a minute just to look at 3 this because one of -- 4 MS. FITZPATRICK: Let's just 5 take a quick break. 6 THE WITNESS: Can I just finish 7 my thought? 8 MS. FITZPATRICK: Sure. 9 A. So, one of the things that 10 happened in the review process is there 11 were so many revisions that the -- that we 12 ended up, the reviewers -- the editors 13 ended up excluding some things, some of 14 the data that we had, and as I was 15 talking, I wasn't sure which of it finally 16 got into the article because we -- because 17 there were so many revisions and no one's 18 ever asked me in this much detail about 19 it. 20 So I'm remembering it, the 21 review process, but not exactly what 22 the -- whether that got into the final 23 document. So I'm going to look at that. 24 MS. FITZPATRICK: Why don't you</p>	<p style="text-align: right;">Page 52</p> <p>1 take a quick look at that. We'll just 2 go off the record and come back when 3 you're ready. 4 (Recess taken.) 5 BY MS. FITZPATRICK: 6 Q. Before we took a break, Doctor, 7 you were going to check on that question 8 you had. 9 Did you come up with an answer 10 to that question? 11 A. Yes. Thankfully, it is in the 12 final paper. 13 Q. So, does that alleviate any 14 question you had about that particular 15 issue and you've satisfied yourself that 16 it is reflected accurately in the final 17 paper? 18 A. Yes. I think I might have said 19 the mean, median and range and it looks 20 like the table only has the median and 21 range. It's a minor correction. 22 Q. Okay. So, I want to talk about 23 that. Why don't you tell me what table 24 you're referring to so we can --</p>

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<p style="text-align: right;">Page 53</p> <p>1 A. I just picked a random one, 2 Table 2. It says "Complications of 3 retropubic or transobturator slings." 4 Q. Okay. So, tell me what Table 2 5 is. 6 A. It's a list of complications 7 that were reported in all of the papers 8 that we read. 9 Q. So, did you go into this process 10 looking only for certain complications, or 11 did you include all of the complications 12 that you saw reflected in the medical 13 literature? 14 A. All of the complications 15 reflected in the medical literature. 16 Q. So you didn't exclude anything 17 at all that you saw as far as a 18 complication? 19 A. No. 20 Q. So, what you've identified 21 here -- 22 A. I'm sorry. It might not be in 23 the table. 24 Q. Okay.</p>	<p style="text-align: right;">Page 54</p> <p>1 A. But between the table and the 2 text, we didn't intentionally exclude 3 anything. 4 Q. Okay. So if something isn't in 5 the table, it may be in the text. The 6 table is just a representation and it's 7 just for ease of looking at what would be 8 significant or common complications; is 9 that right? 10 A. Yes. 11 Q. I want to try and understand 12 what you are doing here. 13 So, if we start with, let's 14 stick with bladder perforation. You have 15 under here pelvic organ perforation, you 16 have bladder, you have N 19411. 17 What is that? 18 A. That's the total number of 19 patients that were -- when we added up all 20 the patients, there were 19,000 -- that we 21 reviewed, there were 19,411 that we -- 22 that where the authors presented data to 23 allow us to understand whether or not they 24 had a perforation.</p>
<p style="text-align: right;">Page 55</p> <p>1 Q. And then you have next to it: 2 "Complication percentage of patients 579." 3 A. That's the number of patients -- 4 let's see here. 5 Q. Is that the numerator? 6 A. That should be the numerator. 7 Q. Okay. And then next to that 8 you've got: "Incidence mean range 2.9" 9 and you got: "0 to 16.1." 10 Can you explain that to me? 11 A. Yes, it means that when we added 12 them all up, the mean was 2.9 and the 13 range was 0 to 16, which is actually my 14 memory was pretty close to that from 15 before. So that some papers had zero, 16 reported zero complications and some 17 reported as many as 16 percent. 18 MS. FITZPATRICK: Just give me 19 one second. 20 (Discussion held off the record.) 21 BY MS. FITZPATRICK: 22 Q. So, Doctor, we were talking 23 about Table 2 and I had a question for you 24 about the column that has the denominator.</p>	<p style="text-align: right;">Page 56</p> <p>1 Why is the denominator different 2 for each of these complications if you 3 considered all of these articles and all 4 of the cases in reaching your conclusions? 5 A. Because not every paper had the 6 methodology to answer the question about 7 complications. 8 So for example, one article 9 might give us the number of patients that 10 they -- that had perforation of the 11 bladder and when we'd have the 12 denominator, so we could do that, we could 13 present that data. That same patient -- 14 that same paper might not have even 15 mentioned the word "urinary fistula," for 16 example. So we don't know if any of those 17 patients had fistulas or not. So we can't 18 include -- we don't include it as a zero. 19 We say we just don't know. So we 20 excluded, we would have excluded that -- 21 those number of patients from the 22 denominator when we're talking about 23 fistulas. 24 Q. Okay. So, it's fair to say, or</p>

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<p style="text-align: right;">Page 57</p> <p>1 correct me if I'm wrong, when you looked 2 at each of these articles, you then sorted 3 them by which articles reported on which 4 complications; is that right? So you'd 5 put all of the articles that dealt with 6 bladder perforation and you looked at 7 those as a subset for your analysis on 8 bladder perforation specifically, correct? 9 A. Yes. 10 Q. And then you again went back to 11 the full pool of articles and you looked 12 for all of the articles that mentioned 13 vaginal perforation and you made a subset 14 of those articles and made your 15 calculations based on those? 16 A. Yes. 17 Q. Is that right? 18 A. Yes. 19 Q. And that's how you reach the 20 numbers which is the complications 21 percentage of patients that is reflected 22 in the middle column; is that right? 23 A. Yes. 24 Q. And that was one way that you</p>	<p style="text-align: right;">Page 58</p> <p>1 went about calculating the percentage of 2 patients who have a potential complication 3 based on what's available in the medical 4 literature; is that right? 5 A. Yes. 6 Q. Now, the next column is 7 "Incident mean range." 8 That's the second way that you 9 went about also checking on the reports of 10 complications and the incidence of 11 complications, correct? 12 A. Yes. 13 Q. Can you explain to me how the 14 methodology for reaching the incidence 15 differs from the methodology used for 16 reaching the complications? 17 A. Sure. In the first case, we 18 counted every single patient, every single 19 patient was counted once. In the 20 incidence, where it says "Incidence mean 21 and range," those -- that we only 22 considered series of patients. So that 23 doesn't include any of the patients 24 with -- that were case reports. It</p>
<p style="text-align: right;">Page 59</p> <p>1 doesn't include any of the patients, for 2 example, that were just a paper on 3 complications. 4 So the numbers in these two 5 columns, even though they both represent 6 means or averages, the numbers could be 7 very different because they're different 8 populations of papers. 9 Q. So, this was the way that you 10 and your co-authors went about presenting 11 the full gamut of information based on two 12 statistical analyses, correct? 13 A. Exactly. 14 Q. And you reported on both the 15 complications and the incidence without 16 consideration to what was higher or lower? 17 You made sure everything was reported 18 here, correct? 19 A. Exactly. 20 Q. In some of these, the numbers 21 are fairly comparable, right? 22 A. Yes. 23 Q. And in some of them there's some 24 divergence in the percentage of patients</p>	<p style="text-align: right;">Page 60</p> <p>1 that you had and the mean. 2 How do you account for that? 3 A. Because in the series, they may 4 not have mentioned a certain complication. 5 So for example, if you're looking at that 6 same column, if you look at neurologic 7 symptoms within six weeks, in the middle 8 column we counted every single patient 9 where they mentioned it. Now, it looks 10 like there were only 42 patients in that 11 particular group where they said these 12 patients had these complications. Whereas 13 in the other article, they could have had 14 a paper with a thousand patients in it, 15 but they didn't even mention whether or 16 not there was a neurologic complication, 17 so we couldn't count that. 18 Q. And in any event, let me look at 19 the range. So, tell me what the range is. 20 A. Well, the range is -- describes 21 what the minimum complication rate was in 22 one series and the maximum in another -- 23 in other series, and the reason that we 24 did that is one of the critiques that you</p>

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<p style="text-align: right;">Page 61</p> <p>1 might apply to this kind of scientific 2 literature is, well, if you just do an 3 average -- if you just do an average, it 4 doesn't tell you about the difference 5 between perhaps, this is a perhaps, people 6 that are really expert surgeons might get 7 a zero complication rate and novices 8 might, you know, get a 15 percent 9 complication rates. 10 So this gives you the range of 11 what you might expect with the same 12 surgeon or groups of surgeons doing the 13 operation. 14 Q. In looking at both your 15 percentage of patients, as well as the 16 mean that you have reported in this 17 article, all of those fall within below 18 the highest reported incident rate on the 19 range; is that right? 20 A. Sure. That makes sense. 21 Q. So, does that reflect that your 22 article is not reporting the highest 23 possible rates of complications associated 24 with any of these complications?</p>	<p style="text-align: right;">Page 62</p> <p>1 A. To the contrary. We describe in 2 the paper that we believe this represents 3 the least possible number of complications. 4 Q. And it's well below -- 5 MS. FITZPATRICK: Well, strike 6 that. I think I already asked you 7 that. 8 Q. Now, this methodology that 9 you've just described, the two different 10 types of methodology, you used that same 11 methodology for each of the complications 12 that you reported in this medical article; 13 is that correct? 14 A. We did. 15 Q. Is it fair to say that this 16 medical article is -- identifies all of 17 the complications that you were able to 18 see that are reported in the medical 19 literature, correct? 20 A. From 2007 to 2014, yes. 21 Q. Now, what I want to ask you is 22 you identify in your Nature Review article 23 specific types of complications. 24 Are those complications that you</p>
<p style="text-align: right;">Page 63</p> <p>1 have also seen with mesh synthetic sling 2 patients in your clinical practice or 3 through your academic experience? 4 A. Yes. 5 Q. In doing this work in 2014 and 6 2015, did you see any complications that 7 were reported here that you didn't also 8 have some clinical experience with? 9 A. Give me a moment. 10 (Pause.) 11 I'm amazed to say that no, I've 12 seen every one of these complications. 13 Q. And do you rely on your clinical 14 experience for your opinions that the 15 TVT-Exact and the Ethicon midurethral 16 slings can cause these types of 17 complications in women? 18 A. They do. 19 Q. In addition to your clinical 20 experience and in addition to what you 21 have presented in the Nature Review 22 article, do you also rely on other 23 peer-reviewed literature from other 24 authors to support your opinions that each</p>	<p style="text-align: right;">Page 64</p> <p>1 of these complications is associated with 2 the polypropylene midurethral slings? 3 A. I mean, it's not a question that 4 the answer is "yes." 5 Q. Sometimes we ask stupid 6 questions. 7 A. Okay. 8 Q. It's 'cause we have to. 9 Now, you walked me through the 10 complication rates for retropubic slings, 11 and what I want to talk to you about is 12 your -- you've reached some opinions on 13 the risk of negative outcome after 14 synthetic midurethral sling implantation 15 for surgery is greater than or equal to 15 16 percent. 17 Do you recall that? 18 A. I do. 19 Q. Can you tell me the methodology 20 that you and your co-authors used to 21 determine that the overall risk of a 22 negative outcome after synthetic 23 midurethral sling implantation surgery is 24 greater than or equal to 15 percent?</p>

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<p style="text-align: right;">Page 65</p> <p>1 A. Sure. First we looked at the 2 reported incidence that we already 3 described. Then we took the chances of 4 the failure of the sling, which would be a 5 negative consequence. So we took the 6 first number was the complications as we 7 reported them. The second number was the 8 chances of just failure, like any 9 operation can fail. The third was the 10 failure for stress incontinence after an 11 operation -- after a complication from a 12 sling, okay. And the fourth -- let me get 13 my numbers right. I think it's the 14 fourth. The fourth was the incidence of 15 refractory overactive bladder, and what we 16 did with that was that we made, again, a 17 very conservative estimate, okay. So we 18 took the number of reported de novo 19 overactive bladder patients and we said 20 that a certain percentage of them are 21 likely to be refractory. And because the 22 trouble is there is no data on that. 23 There's no data that says, that we could 24 find, that says that if you operate on</p>	<p style="text-align: right;">Page 66</p> <p>1 them and they have de novo overactive 2 bladder and you treat them, X number would 3 get better. So I don't have the exact 4 number, but we picked the number of de 5 novo overactive bladder patients and then 6 we took a percentage of that, of patients 7 that are likely to be refractory, and when 8 you add all those numbers up -- then we 9 added a couple of -- there were a few 10 things like bowel injuries and fistulas 11 that are very rare, but we added in a 12 number of that and added all of those up, 13 the methodology, it's in the paper 14 someplace. 15 Q. And that's the same methodology? 16 A. Yeah. 17 Q. Just so I understand, if I'm 18 looking at box 1 on page 8 of your 19 article. 20 A. Okay. 21 Q. It says: "Complications 22 requiring surgery." 23 Is this the list of 24 complications that you would consider a</p>
<p style="text-align: right;">Page 67</p> <p>1 serious complication for the purposes of 2 calculating that 15.3 percent number? 3 A. Yes. 4 Q. Is it fair to say that, or am I 5 accurate in saying that that list of 6 complications, plus the number of sling 7 failures, the percentage of women whose 8 slings simply don't work for them, you 9 calculated that total -- 10 A. No, no, that's in there. The 11 recurrent and/or persistent stress 12 incontinence. 13 Q. Okay. 14 A. That number is -- that's where 15 the number comes from. 16 Q. Okay. Thank you for clarifying 17 that. 18 So, when you say there's a total 19 incidence of serious complications is 15.3 20 percent, is it accurate to say that's the 21 calculation of the overall risk to a woman 22 that one of these things could happen to 23 her if she has a polypropylene midurethral 24 sling implanted?</p>	<p style="text-align: right;">Page 68</p> <p>1 A. I would say it another way. 2 That there's a, I believe, at least a 15 3 percent chance of having a negative 4 outcome from the sling, from putting the 5 sling in. 6 Q. And the negative outcomes would 7 be one of those things that you have 8 identified in Box 1? 9 A. Yes. 10 Q. But it's not your testimony, for 11 example, that 15.3 percent of women who 12 have a midurethral sling will have chronic 13 pain? 14 A. No. 15 Q. Or that 15.3 percent will have a 16 urethral obstruction, correct? 17 A. Correct. 18 Q. It's just the overall chances of 19 having one of these negative outcomes? 20 A. Yes. 21 Q. Now, going back in time, you 22 published this article in late 2015; is 23 that right? 24 A. Yes.</p>

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<p style="text-align: right;">Page 69</p> <p>1 Q. And it was based on medical 2 records 2007 through 2014; is that right? 3 A. Yes. 4 Q. And do you recall that in the 5 summer of 2014, you testified in front of 6 Judge Goodwin in the Southern District of 7 West Virginia in a case involving Mrs. Joe 8 Husky; is that right? 9 A. I have a remote memory of it, 10 yes. 11 Q. Well, I put you on the stand, 12 so. 13 A. No, I did it. 14 Q. So I know that you did it. 15 And at that time, you had not 16 done the statistical analyses and this 17 analysis that's reflected in your Nature 18 article, correct? 19 A. I'm sorry, what was the date? 20 Q. Summer of 2014. 21 A. Correct. 22 Q. So, since you testified in Mrs. 23 Husky's case in the summer of 2014, have 24 you done additional work that you rely on</p>	<p style="text-align: right;">Page 70</p> <p>1 as the basis for your current opinions 2 reflected in this expert report on the 3 incidence of individual complications rate 4 and the overall complication rate? 5 A. Well, of course. That's what 6 this paper is. 7 Q. And this information wasn't 8 available to you and you had not done this 9 analysis at the time of Mrs. Husky's 10 trial, correct? 11 A. Correct. 12 Q. Ethicon has made a statement 13 that you may not -- I'm going to quote 14 you: "Dr. Blaivas may not, quote, merely 15 a year later, quote, purport to be certain 16 about TVT complication rates." 17 Can you tell me why you can be 18 certain about complication rates in August 19 of 2015 when you couldn't be certain about 20 complication rates in the summer of 2014? 21 A. Because we did such an 22 exhaustive search of the literature and 23 this is our best estimate of the minimum 24 complication rate. I emphasize that.</p>
<p style="text-align: right;">Page 71</p> <p>1 Q. And when you call it an 2 estimate, it's an estimate that is based 3 on two different scientifically reliable 4 means for calculating the rates of 5 complication; is that right? 6 A. Yes. 7 Q. And those are the ones that are 8 reflected in Tables 2, 3, 4 and 5 of the 9 report? 10 A. I'll take your word for it. 11 Yes. 12 Q. I just want to make sure that 13 I'm right. 14 A. Okay. 15 Q. Dr. Blaivas, do you believe that 16 the conclusions that you reached in your 17 report and in your Nature article assume 18 the worst case scenario? 19 A. No. As I said, I think it 20 assumes the best case scenario. 21 Q. And do you believe that it errs 22 on the side of opining as to a higher 23 complication rate to better protect a 24 patient?</p>	<p style="text-align: right;">Page 72</p> <p>1 A. No. I think if anything, it 2 errs on the lower complication rate. 3 Q. And is that reflected in the 4 fact that both the complication percentage 5 and the incidence that you report out are 6 lower than the highest rates that you saw 7 in the research that you did? 8 A. Well, in part, but not -- 9 MS. FITZPATRICK: Take a break. 10 (Discussion held off the record.) 11 MS. FITZPATRICK: Can you read 12 back the question and answer? 13 (The requested portion of the 14 record was read by the Court Reporter.) 15 A. Yeah, because we don't expect it 16 to be the highest rate reported, but we 17 know that the studies, that the majority 18 of the studies don't follow the patient 19 long enough to account for all the 20 complications and that there's no registry 21 and there isn't -- and they don't -- there 22 isn't a methodology to specifically look 23 for complications. So because of those 24 three things alone, it's very likely that</p>

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<p style="text-align: right;">Page 73</p> <p>1 the complication rate that we reported is 2 an underestimate of the real number of the 3 complications. 4 Q. Now, Ethicon claims that your 5 Review article cherry-picked data in 6 failing to take into account long-term 7 studies finding TVT complication rates to 8 be much lower. And they then refer to the 9 articles that are identified in Table 1 10 and states that at Table 1 of the article, 11 the authors collected 11 studies 12 purportedly meeting the criteria for 13 inclusion. 14 Do those articles have to do 15 with efficacy and your conclusions about 16 efficacy, or do they have to do with the 17 overall rates of complications? 18 A. The methodology was primarily 19 geared towards efficacy. 20 Q. So, is it accurate to say that 21 simply because something was not included 22 in Table 1, it is incorrect for Ethicon to 23 say that you did not take into account 24 long-term studies that find TVT</p>	<p style="text-align: right;">Page 74</p> <p>1 complication rates to be lower? 2 A. I'm sorry, there was a couple of 3 negatives in there. I'm not sure about 4 that. 5 Q. Okay. Ethicon attempts to use 6 the fact that there were certain articles 7 that you did not consider for efficacy as 8 evidence that you did not use those 9 articles for consideration of safety. 10 Is that accurate? 11 A. It's not accurate. 12 Q. Why not? 13 A. Because one thing I already 14 alluded to is that we only counted the 15 patients once. So if a patient -- I mean, 16 for example, I know one of the articles in 17 there -- when I say "know," let me just 18 double check. 19 (Pause.) 20 For example, the Nielson 21 article -- no, this doesn't answer your 22 question. Excuse me. 23 The answer is "no" because some 24 of the papers that they cited in that --</p>
<p style="text-align: right;">Page 75</p> <p>1 in that deposition or, I think it was a 2 deposition, were papers that were 3 duplicate, so they used the same patients 4 twice, and I already testified that when 5 that happens, we only counted the 6 complication once. 7 And the second thing is that if 8 an article did not mention a complication, 9 that it wasn't included. They didn't say 10 that they even looked for it. 11 And then thirdly, I do remember, 12 again I don't remember the specifics, but 13 there was one or two articles that didn't 14 come up in our search, and I don't know, 15 you know, we did a very methodical search, 16 but we searched thousands of papers and 17 it's not unexpected that one or two 18 wouldn't come up with a search. 19 Q. And is that something that 20 routinely happens in peer-reviewed 21 articles? 22 A. Sure. 23 Q. Does it call into question the 24 reliability of a peer review article?</p>	<p style="text-align: right;">Page 76</p> <p>1 A. I don't believe so. 2 Q. Now, defendants claim that your 3 opinion that the TVT has a minimal 4 complication rate takes into account 5 prolapse devices. 6 Did you look at articles or 7 consider statistics on prolapse devices 8 when reaching your complication rate in 9 this paper? 10 A. We did not look at -- if a paper 11 had -- it's possible that some of the 12 papers had patients with both prolapse and 13 slings, but in the review process, we 14 would have made our best effort to only 15 include those patients that had to do with 16 sling -- that where the complication was 17 from a sling. 18 Q. Is it fair to say that Ethicon's 19 claim that you included prolapse devices 20 in calculating your complication rate is 21 untrue? 22 A. To the best of our ability to 23 make the distinction, it's untrue. 24 MS. FITZPATRICK: Can we go off</p>

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<p style="text-align: right;">Page 77</p> <p>1 the record for a second?</p> <p>2 (Discussion held off the record.)</p> <p>3 BY MS. FITZPATRICK:</p> <p>4 Q. Dr. Blaivas, you participated in</p> <p>5 the committee at the AUA that considered</p> <p>6 the safety and efficacy of midurethral</p> <p>7 slings, correct?</p> <p>8 A. Yes.</p> <p>9 Q. Can you tell me what you did in</p> <p>10 that respect, what you personally did?</p> <p>11 A. Well, we all -- it was a</p> <p>12 complicated process, similar to what I</p> <p>13 testified before. We did a literature</p> <p>14 search. We had inclusion criteria. We</p> <p>15 selected papers that had to do with the</p> <p>16 surgical management of urinary</p> <p>17 incontinence in women. We selected the</p> <p>18 papers and we tabulated the data on safety</p> <p>19 and efficacy, very similar to what we did</p> <p>20 in the Nature Review article for that</p> <p>21 column in the right where we looked at the</p> <p>22 incidence and the range. And we did that</p> <p>23 for all of the known treatments to stress</p> <p>24 incontinence at the time, surgical</p>	<p style="text-align: right;">Page 78</p> <p>1 treatments.</p> <p>2 Q. You didn't author those</p> <p>3 guidelines, correct?</p> <p>4 A. Well, I was one of eleven</p> <p>5 authors.</p> <p>6 Q. Do those guidelines reflect your</p> <p>7 personal opinions or the position of the</p> <p>8 AUA?</p> <p>9 A. It reflected the opinions of the</p> <p>10 AUA.</p> <p>11 Q. Did you disagree with some of</p> <p>12 those opinions?</p> <p>13 A. Yeah, I disagreed with some of</p> <p>14 the conclusions.</p> <p>15 Q. And did you express that during</p> <p>16 your meetings and to others?</p> <p>17 A. I did.</p> <p>18 Q. Is it fair to say that this</p> <p>19 though ended up being a consensus paper</p> <p>20 that doesn't fully and accurately reflect</p> <p>21 your personal views on the safety and</p> <p>22 efficacy of midurethral slings?</p> <p>23 A. That's correct. I was one</p> <p>24 eleven -- I had one-eleventh of the vote.</p>
<p style="text-align: right;">Page 79</p> <p>1 Q. Now, did the AUA conclude that</p> <p>2 mesh products are suitable surgical</p> <p>3 alternatives?</p> <p>4 A. They did.</p> <p>5 Q. What is your opinion as to</p> <p>6 whether mesh products are suitable</p> <p>7 surgical options?</p> <p>8 A. I think they're suitable</p> <p>9 surgical options in a small percentage of</p> <p>10 patients who accept the known risks and</p> <p>11 complications and weigh the risks and</p> <p>12 benefits. But as I said, I contend that</p> <p>13 it's almost impossible to do that because</p> <p>14 those risks are not well-described and not</p> <p>15 well-known by either the doctors or the</p> <p>16 patients.</p> <p>17 Q. When you say it's a suitable</p> <p>18 surgical option in, did you say a limited</p> <p>19 number of patients?</p> <p>20 A. Yes.</p> <p>21 Q. Can you tell me what you mean by</p> <p>22 that?</p> <p>23 A. Well, I think in a -- first of</p> <p>24 all, in patients that are not going to</p>	<p style="text-align: right;">Page 80</p> <p>1 be -- that have no intention of being</p> <p>2 sexually active and whose life expectancy</p> <p>3 isn't that long, so, you know, older</p> <p>4 women, particularly those that can't</p> <p>5 withstand the rigors of an open operation,</p> <p>6 that are not going to be sexually active,</p> <p>7 particularly those that are obese will be</p> <p>8 a much bigger operation to do an</p> <p>9 autologous sling. I think those patients</p> <p>10 are reasonable candidates once -- if they</p> <p>11 accept and are informed of the risks.</p> <p>12 Q. Do you believe though that</p> <p>13 midurethral polypropylene slings are a</p> <p>14 safe first line surgical option for all</p> <p>15 women who suffer from stress urinary</p> <p>16 incontinence?</p> <p>17 A. Well, I don't think it's my job</p> <p>18 to decide for another patient. I don't</p> <p>19 believe -- for the patient. I think the</p> <p>20 patient and the -- the patient needs to be</p> <p>21 informed of the risks and benefits, and if</p> <p>22 they were informed of the risks and</p> <p>23 benefits, I think they would realize that</p> <p>24 it's not safe and it's not worth the risk.</p>

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<p style="text-align: right;">Page 81</p> <p>1 I might not have answered. What 2 was the actual question? 3 Q. You had said that you believed 4 it was an appropriate surgical option for 5 a limited number of patients. You 6 identified who those patients were. 7 What I was asking was do you 8 believe that the Ethicon midurethral 9 slings are a suitable safe surgical option 10 as a first line treatment for all women 11 who have stress urinary incontinence? 12 A. I do not. 13 Q. And is that based on your 14 clinical experience in treating women who 15 have mesh-related complications? 16 A. Yes. 17 Q. And is it based -- 18 A. Excuse me. And my knowledge of 19 how likely they are to occur. 20 Q. Is it based on your review of 21 the medical literature discussing the 22 potential complications and the incidence 23 of complications that are associated with 24 midurethral slings?</p>	<p style="text-align: right;">Page 82</p> <p>1 A. Yes. 2 Q. And that includes a review of 3 literature that reports few complications 4 and literature that reports many 5 complications, correct? 6 A. Yes. 7 Q. And you take into account for 8 your opinions medical articles that report 9 low rates of complications when reaching 10 your opinions, correct? 11 A. Yes. 12 Q. And you took all of those into 13 account, to the best of your ability, when 14 conducting your Nature Review, correct? 15 A. I did. 16 Q. And you didn't exclude any such 17 reports simply because they had a low 18 incidence of complication reported in 19 them, correct? 20 A. Correct. 21 Q. Do you also base that opinion on 22 your clinical experience in implanting 23 autologous slings or doing non-mesh 24 surgery for SUI patients?</p>
<p style="text-align: right;">Page 83</p> <p>1 A. Yes. 2 Q. Do you also base your opinion on 3 medical literature concerning the 4 complications associated with the 5 autologous fascial sling and other 6 non-mesh surgeries to correct SUI? 7 A. I do. 8 Q. Now let's go back to the AUA. 9 Does the AUA recognize an 10 autologous fascial sling as a suitable 11 surgical option for women who have stress 12 urinary incontinence? 13 A. It does. 14 Q. Does it recognize other non-mesh 15 procedures as suitable surgical options 16 for women who have stress urinary 17 incontinence? 18 A. It does. Yes, it does. 19 Q. And what are those? 20 A. Autologous fascial sling, a 21 Burch, it doesn't really -- also 22 Marshall-Marchetti-Krantz, and other 23 retropubic kind of operations and 24 midurethral -- excuse me, periurethral</p>	<p style="text-align: right;">Page 84</p> <p>1 injections, and homologous and xeno -- 2 homologs and xenografts. 3 Q. Does the AUA conclude that the 4 or look at -- 5 MS. FITZPATRICK: Strike that. 6 Q. Does the AUA conclude that the 7 polypropylene midurethral sling is a safer 8 surgical option to some of the non-mesh 9 surgeries? 10 A. It does not. 11 Q. And does the AUA guidelines that 12 you were involved with suggest that 13 physicians such as yourself and others 14 should only consider polypropylene 15 midurethral slings as a suitable surgical 16 option for -- 17 A. It does not. 18 Q. In that respect, do you agree 19 with the AUA that these non-mesh 20 procedures are suitable surgical options 21 for women who have stress urinary 22 incontinence? 23 A. Of course. 24 Q. Separate and apart from what's</p>

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<p style="text-align: right;">Page 85</p> <p>1 reflected in the AUA, do you believe that</p> <p>2 the non-mesh surgical options, and</p> <p>3 particularly the autologous fascial sling,</p> <p>4 are safer procedures for women who have</p> <p>5 stress urinary incontinence generally?</p> <p>6 A. I do.</p> <p>7 Q. Tell me what the basis for that</p> <p>8 opinion is.</p> <p>9 A. Well, because the autologous</p> <p>10 slings simply don't have any of the</p> <p>11 devastating kind of complications that we</p> <p>12 talk about. For practical purposes, no</p> <p>13 refractory pain and there's, for practical</p> <p>14 purposes, no erosion, and for practical</p> <p>15 purposes, there's no fistulas. I mean,</p> <p>16 the really serious complications, the</p> <p>17 autologous sling does not have.</p> <p>18 Q. Now, Ethicon has asserted that</p> <p>19 you base your opinions on the benefits of</p> <p>20 autologous slings solely on your own</p> <p>21 unreliable personal experiences.</p> <p>22 Is that correct?</p> <p>23 A. I wonder why they call my</p> <p>24 published peer-reviewed articles</p>	<p style="text-align: right;">Page 86</p> <p>1 unreliable, but no, that's not correct.</p> <p>2 Q. What else do you base it on?</p> <p>3 A. The peer review literature and</p> <p>4 speaking with my associates.</p> <p>5 Q. Okay.</p> <p>6 A. My colleagues.</p> <p>7 Q. Is there any specific -- let me</p> <p>8 ask you this.</p> <p>9 When reaching your opinions</p> <p>10 concerning the safety of autologous</p> <p>11 fascial slings, did you consider all</p> <p>12 reported medical articles that you had</p> <p>13 seen concerning the complications rates</p> <p>14 associated with autologous fascial slings?</p> <p>15 A. I did.</p> <p>16 Q. And that formed one basis of</p> <p>17 your opinions, correct?</p> <p>18 A. Yes.</p> <p>19 Q. And you didn't simply adopt or</p> <p>20 form your opinion based on reading of a</p> <p>21 single article, correct?</p> <p>22 A. Correct.</p> <p>23 Q. Did you look at the totality of</p> <p>24 the articles out there that supported your</p>
<p style="text-align: right;">Page 87</p> <p>1 opinions?</p> <p>2 A. I looked at the totality, but I</p> <p>3 also looked at the severity of the</p> <p>4 complications and there's no question in</p> <p>5 my mind that the severity of the</p> <p>6 complications on average are much worse in</p> <p>7 synthetic slings than in autologous</p> <p>8 slings.</p> <p>9 Q. Okay.</p> <p>10 A. And also the ease with which</p> <p>11 they can be corrected are much easier and</p> <p>12 predict -- more predictable in the</p> <p>13 autologous sling compared to the mesh</p> <p>14 sling.</p> <p>15 Q. Okay. Now, you offered opinions</p> <p>16 concerning mesh degradation, shrinkage and</p> <p>17 other deformation, correct?</p> <p>18 A. Yes.</p> <p>19 Q. Have you seen deformed mesh that</p> <p>20 you've explanted from women?</p> <p>21 A. Of course.</p> <p>22 Q. Have you seen mesh that's shrunk</p> <p>23 that you've explanted from women?</p> <p>24 A. Well, I've seen the mesh scar</p>	<p style="text-align: right;">Page 88</p> <p>1 complex.</p> <p>2 Q. And mesh degradation, have you</p> <p>3 seen mesh falling apart when you take it</p> <p>4 out of women?</p> <p>5 A. I have.</p> <p>6 Q. Is your clinical experience in</p> <p>7 observing each of these phenomenon a basis</p> <p>8 for your opinion that each of those things</p> <p>9 can happen?</p> <p>10 A. Yes.</p> <p>11 Q. In addition to your clinical</p> <p>12 experience, is this an issue that you also</p> <p>13 studied in your Nature Review article?</p> <p>14 A. Yes.</p> <p>15 Q. Did you rely on the conclusions</p> <p>16 that you reached in your Nature Review</p> <p>17 article as a separate basis for your</p> <p>18 conclusions about mesh degradation,</p> <p>19 shrinkage and deformation?</p> <p>20 A. I did.</p> <p>21 Q. And can you tell me what you and</p> <p>22 your co-authors did to study mesh</p> <p>23 degradation, shrinkage, and deformation in</p> <p>24 your Nature Review article?</p>

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<p style="text-align: right;">Page 89</p> <p>1 A. Well, Dr. Latovlev actually that 2 did that. I mean, he wrote that part of 3 the article, and he himself has done 4 extensive studies both of a explanted mesh 5 looking at the gross specimen for 6 stiffness and deformation, looking at the 7 light microscopic and also the 8 ultramicroscopic characteristics of the 9 mesh, and he concluded based on his own 10 work and that of many others in the 11 literature that mesh degrades in vivo. 12 Q. Did he also conclude that mesh 13 shrinks in vivo? 14 A. Yes. 15 Q. And did he also conclude that 16 mesh can deform in vivo? 17 A. Yes. 18 Q. So you talked about what Dr. 19 Latovlev did in your paper. 20 Is there additional literature 21 in the peer review that you are aware of 22 that establishes that mesh can degrade, 23 shrink and deform? 24 A. Yes, there's a lot of -- there</p>	<p style="text-align: right;">Page 90</p> <p>1 are a number of studies in the literature. 2 Q. Have you cited to those as part 3 of your reliance list in this case? 4 A. I have. 5 Q. And those are the basis for your 6 opinions? 7 A. Yes. 8 Q. I want to go back to just a 9 general question. 10 Ethicon has raised questions 11 about the methodology that you have used 12 to reach your opinions in this case. 13 A. I'm sorry, I missed the first 14 part of your sentence. 15 Q. Ethicon has raised issues with 16 the methodology that you have used to 17 reach your opinions in this case. 18 Did you rely on your clinical 19 experience as part of your basis for each 20 of the opinions that you hold? 21 A. I did. 22 Q. And did you rely on your own 23 peer-reviewed literature as part of the 24 basis for the opinions?</p>
<p style="text-align: right;">Page 91</p> <p>1 A. I did. 2 Q. And did you rely on other peer 3 review literature as part of the basis for 4 your opinions in this case? 5 A. I did. 6 Q. Is it fair to say that each of 7 your opinions depends on all three of 8 those aspects of your experience as its 9 bases? 10 A. It did, but when I heard your 11 question, I'm trying to understand. 12 There's no controversy about whether these 13 things exist except for possibly the 14 degradation. Everything's well documented 15 in the literature. I think the only thing 16 they could possibly contest is how often 17 that occurs, but the published literature, 18 exclusive of anything that I said, I mean, 19 we -- you know, we cited the New England 20 Journal of Medicine, the Journal of 21 Urology, the most reputable journals, you 22 know, show, for example, a five to six 23 percent incidence of perforation. Every 24 review article has shown one or two</p>	<p style="text-align: right;">Page 92</p> <p>1 percent, at least, urethral obstruction, 2 revision surgery. Those things are 3 indisputable. There's no controversy 4 about that. 5 The only thing -- the only thing 6 they could possibly argue with is the 7 actual incidence. 8 Q. And you've laid out for us what 9 your methodology in calculating that 10 incidence is, correct? 11 A. I think in much greater detail 12 than any of the other articles that talk 13 about complications. 14 Q. Let me just go back. 15 Now, Ethicon is not here at this 16 deposition today, correct? 17 A. Correct. 18 Q. Now, this deposition was 19 originally noticed by Ethicon, and you are 20 here in deposition today because Ethicon 21 asked you to be in deposition, correct? 22 A. Correct. 23 Q. And if Ethicon had chosen to 24 show up for this deposition, they could</p>

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<p style="text-align: right;">Page 93</p> <p>1 have asked you any questions that they 2 wanted based on your TVT-Exact report, 3 correct? 4 A. Yes. 5 Q. And they chose not to do so 6 today? 7 A. I believe so. 8 MS. FITZPATRICK: That's all 9 that I've got. 10 I just would like to mark as 11 Exhibit 2 the original notice of 12 deposition of Dr. Blaivas from Ethicon 13 that was dated August 25th, 2016. 14 (Blaivas Exhibit 2, Notice To 15 Take Deposition of Jerry Blaivas, M.D. 16 dated August 25, 2016, was marked for 17 identification, as of this date.) 18 MS. FITZPATRICK: And mark as 19 Exhibit 3 the amended notice to take 20 the deposition of Dr. Blaivas that we 21 filed today, August 29th, immediately 22 following Ethicon's withdrawal of its 23 notice. 24 (Blaivas Exhibit 3, Amended</p>	<p style="text-align: right;">Page 94</p> <p>1 Notice To Take Deposition of Jerry 2 Blaivas, M.D. dated August 29, 2016, 3 was marked for identification, as of 4 this date.) 5 BY MS. FITZPATRICK: 6 Q. Doctor, looking at this, which 7 is Exhibit 3, the subject matter is 8 general opinions regarding midurethral 9 sling products. We focused today on your 10 TVT-Exact report, correct? 11 A. Yes. 12 Q. And some of those opinions are 13 unique to the TVT-Exact, correct? 14 A. Yes. 15 Q. But some of those opinions will 16 span all of your polypropylene midurethral 17 sling products, correct? 18 A. Yes. 19 Q. Including your opinions on the 20 methodology that you used in both your 21 Nature article and the methodology that 22 you used in your report, correct? 23 A. Yes. 24 Q. And that's common to all</p>
<p style="text-align: right;">Page 95</p> <p>1 reports, but also to the TVT-Exact? 2 A. Yes. 3 MS. FITZPATRICK: Now I'm done. 4 (Time noted: 3:14 p.m.) 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24</p>	<p style="text-align: right;">Page 96</p> <p>1 A C K N O W L E D G M E N T 2 3 STATE OF) 4 :ss 5 COUNTY OF) 6 7 I, JERRY G. BLAIVAS, M.D., hereby 8 certify that I have read the transcript of 9 my testimony taken under oath in my 10 deposition of August 29, 2016; that the 11 transcript is a true and complete record 12 of my testimony, and that the answers on 13 the record as given by me are true and 14 correct. 15 16 17 18 JERRY G. BLAIVAS, M.D. 19 Signed and subscribed to before me this 20 _____ day of _____, 2016. 21 22 23 Notary Public, State of 24</p>

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<div style="text-align: right;">Page 97</div> <div style="text-align: center;">ERRATA</div> <div style="text-align: center;">PAGE / LINE / CHANGE / REASON</div> <div> 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 </div>	<div style="text-align: right;">Page 98</div> <div style="text-align: center;">CERTIFICATE</div> <div> 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 </div> <p>STATE OF NEW YORK COUNTY OF NEW YORK</p> <p>I, Marie Foley, RMR, CRR, a Certified Realtime Reporter and Notary Public within and for the State of New York, do hereby certify:</p> <p>THAT JERRY G. BLAIVAS, M.D., the witness whose deposition is hereinbefore set forth, was duly sworn by me and that such deposition is a true record of the testimony given by the witness.</p> <p>I further certify that I am not related to any of the parties to this action by blood or marriage, and that I am in no way interested in the outcome of this matter.</p> <p>IN WITNESS WHEREOF, I have hereunto set my hand this 3rd day of September, 2016.</p> <p style="text-align: right;">_____ MARIE FOLEY, RMR, CRR</p>
<div style="text-align: right;">Page 99</div> <div style="text-align: center;">LAWYER'S NOTES</div> <div style="text-align: center;">PAGE / LINE</div> <div> 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 </div>	